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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,006	06/14/2001	Yoji Sakagami	026350-058	4690

7590 07/29/2003
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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/29/2003

127

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/880,006

Applicant(s)

SAKAGAMI ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 2-11, 13, 14, 16, 17, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 12, 15, 18, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-22 are pending and Claims 2-11, 13-14, 16-17, and 19-20 are withdrawn.

Rejection of Claim 1 under 35 U.S.C. 101 is withdrawn in view of Applicant's amendments.

Election/Restrictions

Applicant asserts that the inclusion of Groups I-V would not constitute an additional burden upon the Examiner (response page 6). Applicant's is reminded that up to ten sequences searched was meant to apply to EST sequences not promoter or coding sequences as indicated in the previous office action.

Claim Rejections - 35 USC § 112

Claims 1, 12, 15, 18, and 21 remain and new Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/03/2002. Applicant's arguments filed May 5, 2003 have been considered but are not deemed persuasive.

Applicant asserts that the amendments have rendered moot the notion that applicants were not in possession of the claimed invention (page 7). However, part (c) of Claim 1 does not specify the degree of stringency, and so reads on a multitude of sequences which would hybridize to the sequences of part (a) under conditions of low or moderate stringency. The specification provides no common structural features, i.e. conserved sequences, common to the broad genus, which are correlated with function, i.e. promoter activity. Furthermore, Applicant

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has not described any isolated nucleic acid sequence having 90% sequence identity to SEQ ID NO: 1, or the broad genus encompassing these sequence variants.

Claims 1, 12, 15, 18, and 21 remain and new Claim 22 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the promoter of SEQ ID NO: 1 and promoter fragments of SEQ ID NO: 1 (-1911 to -1, -1034 to -1, -563 to -1, -148 to -1, -3359 to -1034, and -1911 to -1034) driving GUS expression in rice cells transformed with said fragments, does not reasonably provide enablement for sequences hybridizing under conditions of unspecified stringency or an isolated nucleic acid sequence which exhibits 90% homology with the isolated nucleic acid sequence of Claim 1, and a method of activating expression in plant cells other than rice or any plants transformed with said promoter or DNA that hybridizes to SEQ ID NO: 1 or an isolated nucleic acid sequence which exhibits 90% homology with the isolated nucleic acid sequence of Claim 1, by incorporation upstream of an exogenous or endogenous structural gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant asserts that one of skill in the art could make the claimed invention (response page 7). Given the unpredictability of promoter identification, sequence modification, or evaluation of function in transformed plants, and the lack of guidance as discussed in the last office action; although one of skill in the art can readily transform plants and make promoter deletions and substitutions one would not know based upon Applicant's disclosure which embodiments could be predictably eliminated, and thus undue experimentation would have been required to practice the claimed invention.

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Claims 1, 12, 15, 18, and 21 remain and new Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/03/2002. Applicant's arguments filed May 5, 2003 have been considered but are not deemed persuasive.

At Claim 1, line 10, "stringent conditions" is indefinite. It is not clear whether conditions of low, moderate, or high stringency are to be used.

At Claim 22, line 2, "an isolated nucleic sequence" should read --the isolated nucleotide sequence--.

At Claim 22, line 1, "exhibits 90% homology" is indefinite. Specifically "homology" is often used to express evolutionary relationships between biological macromolecules and thus embraces properties other than the one to one correspondence of identical residues in the same position within a polynucleotide or polypeptide sequence. Changing "homologous" to --sequence identity-- would obviate the rejection.

Claim Rejections - 35 USC § 102

Claims 1 and 12 remain and new Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Yang H. *et al.* GenBank Accession Number AB026837 submitted April 28, 1999. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/03/2002. Applicant's arguments filed May 5, 2003 have been considered but are not deemed persuasive.

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Applicant's assertion that the reference was published December 19, 2000 is in error (response page 8). Applicant's attention is directed to the submission of the sequence, dated April 28, 1999, to a public database. Visual inspection indicates that nucleotides 1-3359 of the submitted reference match nucleotides 1 to 3359 (-3359 to -1) of SEQ ID NO: 1.

Claim Rejections - 35 USC § 103

Claims 1, 12, 15, 18, and 21 remain and new Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang H. *et al.* GenBank Accession Number AB026837 submitted April 28, 1999 in view of Christensen A. *et al.* Transgenic Research, 1996, Vol. 5 pp. 213-218. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/03/2002. Applicant's arguments filed May 5, 2003 have been considered but are not deemed persuasive.

Applicant asserts that the rejection over Yang in view of Christian has been obviated because the Yang is not a proper 102(b) rejection (response page 9). See arguments *supra*.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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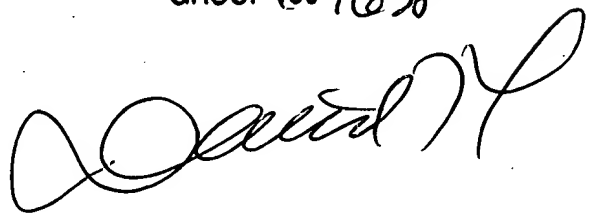
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Russell Kallis Ph.D.
July 25, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~-1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and title.